

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/582,119	06/22/00	BENNER	G BEIERSDORF62

HM12/0501

NORRIS MC LAUGHLIN & MARCUS
660 WHITE PLAINS ROAD
TARRYTOWN NY 10591-5144

EXAMINER

BERMAN, A

ART UNIT	PAPER NUMBER
1619	9

DATE MAILED: 05/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/582,119	BENNER ET AL.
	Examiner Alycia Berman	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of the preliminary amendment filed June 22, 2000 and the requests for corrected filing receipt filed August 15, September 1, September 15 and November 20, 2000. Claims 2-8 have been amended. Claims 1-8 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is confusing because it is not written using proper grammatical English. It appears to contain more than one sentence.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

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remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 5 recites the broad recitation "0.1-10.0% by weight", and the claim also recites "preferably 0.5-6.0% by weight" which is the narrower statement of the range/limitation. Claim 6 recites the broad recitation "0.1-10.0% by weight", and the claim also recites "preferably 0.5-6.0% by weight" which is the narrower statement of the range/limitation. Claim 7 recites the broad recitation "7:3 to 3:7", and the claim also recites "preferably 2:1 to 1:2, particularly preferably of about 1:1" which is the narrower statement of the range/limitation.

6. Claim 2 provides for the use of components (I) and (II) but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 1,437,366 (366).

FR '366 discloses oil-in-water emulsions comprising 13% or 25% glyceryl stearate citrate, 3% cetyl alcohol and an aqueous phase with 70% water. See Examples XI and XII. The emulsion of Example XI contains 70% of an aqueous phase. Therefore, the lipid phase makes up as much as 30% of the emulsion. The amounts of components fall within the ratio ranges instantly claimed.

9. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 3820693 A1 (693).

DE '693 discloses oil-in-water emulsions comprising Lamegin® ZE 30, which contains the citric acid ester of glycerin monostearate, octyldecanol and cetyl alcohol. See the abstract, page 2, line 65 to page 3, line 9 and page 3, lines 54-59. For 0.5% citric ester, see Table 1 at page 4. The amounts of components fall within the ratio ranges instantly claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 1,437,366 (366) in combination with DE 3820693 A1 (693).

FR '366 teaches all the limitations of the claims as stated above. It does not teach 0.1-10% by weight of the citrate ester. DE '693 teaches all the limitation of the claims as stated above.

FR '366 teaches oil-in-water emulsions comprising glyceryl stearate citrate and a fatty alcohol. DE '965 teaches emulsions comprising 0.5% glyceryl stearate citrate and a fatty alcohol. It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of FR '366 using an optimal amount of citrate ester as taught by DE '693 expecting to obtain a stable oil-in-water emulsion.

13. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either FR 1,437,366 (366) or DE 3820693 A1 (693) alone or together in combination with US 5,770,185 (185).

FR' 366 teaches all the limitations of the claims as stated above. It does not teach cetylstearyl alcohol or 0.1-10% by weight of the esters of citric acid and glycerides of fatty acids. DE '963 teaches all the limitations of the claims as stated above. It does not teach cetylstearyl alcohol.

US '185 discloses a composition comprising an ester of a hydroxycarboxylic acid with fatty acid esters with 12-22 carbon atoms (col. 1, lines 42-47). For citric acid as the hydroxycarboxylic acid, see column 2, lines 1-4. For partial esters of stearic acid, see column 2, lines 10-17. For esterification products of citric acid and glycerol monostearate, see column 2, lines 35-43. US '185 also discloses that the esters disclosed by FR 1,437,366 are suitable for use in the compositions (col. 2, lines 47-49). Lamegin ZE 309, a citric acid ester of the monoglyceride of hydrogenated tallow fatty acid, is disclosed at column 2, lines 52-54. The amount of hydroxycarboxylic acid partial ester is around 0.5-10% by weight (col. 2, lines 63-65). For aqueous emulsions, see column 3, lines 4-5 and lines 21-22 for low viscosity emulsions. For co-emulsifiers such as cetostearyl alcohol, see column 3, lines 37-39. See also example 1 at column 4 for a composition comprising cetostearyl alcohol and Lamegin® ZE 309.

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FR '366 teaches oil-in-water emulsions comprising glyceryl stearate citrate and a fatty alcohol. DE '965 teaches emulsions comprising glyceryl stearate citrate and a fatty alcohol. US '185 teaches topical compositions comprising esters of citric acid and glycerides of fatty acids and cetylstearyl alcohol.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of either FR '366 or DE '963 each and substitute cetylstearyl alcohol as taught by US '185 expecting to obtain a stable emulsion.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-8 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 09/581,413. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to compositions, preferably emulsions, comprising one or more partially

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neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid (glyceryl stearate citrate), one or more branched or unbranched C12-40 fatty alcohols (cetylstearyl alcohol), a lipid phase and a water phase.

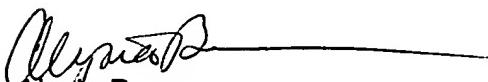
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alycia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4456 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alycia Berman
Patent Examiner
April 19, 2001


DIANA DUDASH
SUPPLYORY PATENT EXAMINER
TECHNOLOGY CENTER 1600